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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,201	06/25/2003	Tammy Burd Mehta	100/05231	4356

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CALIPER LIFE SCIENCES, INC.
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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,201	Applicant(s) BURD MEHTA ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) 4-6 and 12-16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 7-11 and 17-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 07/29/2005 is acknowledged and entered.
2. Claims 2-20 were added by the preliminary amendment filed on 12/23/2003.
3. Claims 1-20 are pending.

Election/Restrictions

4. Applicant's election of Group I (Claims 1-11, and 17-20) in the reply filed on 07/29/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
5. Claims 12-16 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *a nonelected invention*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/29/2005.
6. Applicant is reminded that since applicant has elected to prosecute the product (device of Group I: Claims 1-11, and 17-20), applicants are advised that in accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)}, and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996)}, in the event that a product claim (Group I:

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Claims 1-11, and 17-20) is found to be allowable, the claim method of use (Group II: Claims 12-16) *which is of the same scope as the allowed product claim* may be rejoined with the allowed product claim.

7. Applicant has elected the following species for the elected invention (Claims 1-11, and 17-20) in the reply filed on 7/29/2005:

- a. A single specific species of reagents. Applicant elected nucleic acid of claim 3.
- b. A single specific species of beads. Applicant elected DNA coated microspheres of claim 7.
- c. A single specific species of device that is if the device requires a fluid system or not. Applicant elected that the device requires a fluid system.

8. Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/29/2005.

9. Claims 1-3, 7-11, and 17-20 are under consideration in this Office Action.

Priority

10. This instant application is a CON of 09/510,626 filed 02/22/2000, which claims benefit to three provisional applications. They are 60/121,223 filed 02/23/1999, 60/127,825 filed 04/05/1999, and 60/128,643 filed 04/09/1999. This instant application is granted the benefit of

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priority for 09/510,626 under 35 U.S.C 120, and for all three provisional applications, i.e. 60/121,223, 60/127,825, and 60/128,643, under 35 U.S.C 119(e).

Information Disclosure Statement

11. The information disclosure statements (IDS) filed on 12/23/2003 have been reviewed, and its references have been considered as noted on PTO-1449 forms.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 2, 8-11, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. (US Patent 6,007,690; *filing date of 07/30/1996*).

Nelson et al. disclose an integrated microfluidic devices comprises at least an enrichment channel and a main electrophoretic flowpath (see e.g. Abstract; col. 2, lines 48-67; col. 4, lines 3-11). In one type of microfluidic device shown in fig. 3A, the microfluidic device comprises main electrophoretic flowpath (refers to instant claimed reagent flow region)(ref. # 31), a reservoir at each end of the main electrophoretic flowpath (ref. # 32 and 33), and an enrichment channel (refers to instant claimed particle capture region)(ref. # 34) in fluid communication with

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the main electrophoretic flowpath (see e.g. col. 12, lines 10-24; fig. 3A). As shown in fig. 3A, the enrichment channel is larger than the main electrophoretic flowpath (refers to instant claimed limitation that '*the particle capture region has increased depth relative to the reagent flow region*'). The enrichment channel comprises an inlet, an outlet, and an internal enrichment medium for enriching a particular fraction of a sample (see e.g. col. 4, lines 43-56). The enrichment medium includes media such as beads coated with antibodies (refers to instant claimed a set of particle, and instant claim 2)(see e.g. col. 5, lines 12-49; col. 6, lines 14-29). The depth of the main electrophoretic flowpath is in the range of 1 μ m to 200 μ m (refers to instant claims 9-11)(see e.g. col. 8, lines 46-62). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19)(see e.g. col. 6, line 54 thru col. 7, line 7; col. 8, line 63 thru col. 9, line 10). Although Nelson et al. do not disclose the size of the beads, Nelson et al. disclose using commercially available bead, i.e. Dynabead®. The size of these commercially available bead ranges from 1 μ m to 4.5 μ m as evidence by the product information of Dynabead®. Thus the device of Nelson et al. anticipates the presently claimed apparatus.

14. Claims 1-3, 7, 9-11, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Patent 5,942,443; *filing date of 06/28/1996*)

The applied reference has common inventors (i.e. John Wallace Parce, Anne R. Kopf-Sill, and Luc. J. Bousse) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

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disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Parce et al. disclose microfluidic devices and methods for performing high-throughput screening assays (see e.g. Abstract; col. 2, lines 36-43; col. 3, lines 3-51). In one type of apparatus shown in figure 3, the microfluidic device comprises a substrate (ref. # 302), a series of parallel reaction channels (ref. # 312-324), sample injection channel (refers to instant claimed reagent flow region)(ref. #304), seeding channel (ref. #306), collection channel (ref. #308), and bead resting wells (ref. #326-338) (refers to instant claimed particle capture region)(see e.g. col. 16, line 1 thru col. 18, line 65; figs. 3 and 4). As illustrated in figures 3 and 4, the bead resting wells that are located at the intersection of the sample injection channel and the parallel reaction channels are larger than the sample injection channel and the parallel reaction channels in order retain the bead refers to instant claimed limitation that ‘*the particle capture region has increased depth relative to the reagent flow region*’). The bead comprises immobilized test compound that include nucleic acids (refers to instant claims 2, 3, and 7)(see e.g. col. 6, line 60 thru col. 7, line 19; col. 16, line 47-52). The dimension of the channels ranges from 1 μ m to 500 μ m (refers to instant claims 9-11)(see e.g. col. 3, lines 8-10; col. 8, lines 43-57). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19) and a computer system (refers to instant claim 20)(see e.g. col. 12, lines 11-44; col. 21, lines 7-11). Thus the device of Parce et al. anticipates the presently claimed apparatus.

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15. Claims 1-3, 7, 9-11, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (US Patent 6,429,025 B1; *filing date of 03/19/1998*)

The applied reference has common inventors (i.e. John Wallace Parce, Anne R. Kopf-Sill, and Luc. J. Bousse) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Parce et al. disclose microfluidic devices and methods for performing high-throughput screening assays (see e.g. Abstract; col. 3, line 19 thru col. 4, line 15; col. 10, lines 15-34). In one type of apparatus shown in figure 3, the microfluidic device comprises a substrate (ref. # 302), a series of parallel reaction channels (ref. # 312-324), sample injection channel (refers to instant claimed reagent flow region)(ref. #304), seeding channel (ref. #306), collection channel (ref. #308), and bead resting wells (ref. #326-338) (refers to instant claimed particle capture region)(see e.g. col. 25, line 17 thru col. 28, line 16; figs. 3 and 4). As illustrated in figures 3 and 4, the bead resting wells that are located at the intersection of the sample injection channel and the parallel reaction channels are larger than the sample injection channel and the parallel reaction channels in order retain the bead refers to instant claimed limitation that ‘*the particle capture region has increased depth relative to the reagent flow region*’. The bead comprises immobilized test compound that include nucleic acids (refers to instant claims 2, 3, and 7)(see e.g. col. 9, lines 12-43; col. 25, line 65 thru col. 26, line 3). The dimension of the channels ranges from 1µm to 500 µm (refers to instant claims 9-11)(see e.g. col. 3, lines 39-41; col. 16,

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lines 6-20). The device also comprises a fluid direction means such as a pump or electrodes (refers to instant claimed fluid direction system, and instant claims 18 and 19) and a computer system (refers to instant claim 20)(see e.g. col. 19, lines 48 thru col. 20, line 14; col. 31, lines 14-22). Thus the device of Parce et al. anticipates the presently claimed apparatus.

Double Patenting

16. Claims 1-3, 7-11, and 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14, 19, 22, 32-34, 36, 64, and 67 of U.S. Patent No. 6,632,655 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of U.S. Patent No. 6,632,655 B1 has overlapping scope since the device of the instant application is generic to the device of the presently claimed device of U.S. Patent No. 6,632,655 B1, or in other words, claims 1-3, 7-11, and 17-20 anticipated by claims 1, 14, 19, 22, 32-34, 36, 64, and 67 of U.S. Patent No. 6,632,655 B1. Specifically, the structural features of both devices are a body structure having a microscale cavity disposed therein; a sets of particles disposed within the microscale cavity, wherein said sets of particles are flowable, retained in position within the microscale cavity, and are beads; a fluid direction system; and a control system. Thus, the examined claims would have been obvious over the claims of U.S. Patent No. 6,632,655 B1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810.

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The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00;
Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
September 16, 2005


PADMASHRI PONNALURI
PRIMARY EXAMINER